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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,606	12/08/2003	Patrick J. Sweeney	029815-0105	4015

26371 7590 12/01/2009
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EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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12/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/730,606	Applicant(s) SWEENEY, PATRICK J.	
	Examiner Alvin J. Stewart	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-23 and 42-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-23 and 76-78 is/are allowed.
- 6) ☒ Claim(s) 42-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments regarding the method claims 19-23 and 76-78 have been fully considered and they are persuasive. Claims 19-23 and 76-78 are allowed.

Applicant's arguments regarding claims 42-75 have been fully considered but they are not persuasive.

After a careful review of the Applicant's argument disclosing that the two references are silent with respect to the removal of a shaft without decoupling the head from the body and without removing the body and head from the patient's body, the Examiner believes that the arguments are moot because the applicant's representative is only disclosing the article. During the article claims, the Applicant's representative is only disclosing an implant having a body, a head and a plurality of modular shafts that can be replaced by new shafts. The Examiner only needs to find a reference that is capable of removing and replace a shaft with a new shaft without decoupling the head from the body and without removing the body and head from the patient's body. Muhlhausler et al clearly disclose a shaft capable of being removed from the upper section of the body (30) and the body (30) still held in the intramedullary cavity. However, it seems like the elongated head (40) covers part of the opening (34) of the body (see Fig. 2) and it seems like the head has to be removed from the body before the shaft can be removed. However, Dwyer et al discloses a rounded head small enough to be attached to the head of the Muhlhausler et al reference (the Dwyer et al reference can be used in a hip or shoulder prosthesis) and the shaft can be removed without decoupling the head from the body. For the above reasons, the Examiner maintains the previous rejection.

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The Examiner is allowing the method claims 19-23 and 76-78 because the above references does not disclose the method steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhlhausler et al 6,524,342 B1 in view of Dwyer et al US Patent 7,122,056 B2.

Muhlhausler et al discloses an implant having a body (30) having a central canal (34) and coupled to an articular surface; a shaft (10) is coupled to the body and the shaft can be removed from the patient after implantation of the prosthesis without removing the body and a locking element (20 or 15).

However, Muhlhausler et al does not disclose the step of creating an access aperture, removing a shaft and replaced it with a second shaft and closing the access aperture and is not capable of removing the shaft 10 without removing the head 40 from the body 30.

Dwyer et al discloses an implant having a body (100) having a central canal (36) and coupled to an articular surface (ball connected to neck element 26, element 26 is connected to insert 12 and the other surface of the insert 12 is connected to the central canal (36) of body (14); a shaft (18) is coupled to the body and the shaft can be removed from the patient after implantation of the prosthesis without removing the body.

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Additionally, the device is configured for replacing a hip joint or is capable of being inserted into a shoulder joint. Additionally, the shaft can be called a nail.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Muhlhausler et al reference by changing the oblong head with the circular head of the Dwyer et al reference in order to fit the prosthesis to a regular acetabular cup in a patient's hip instead of only being inserted into a shoulder joint.

Regarding the opening and closing of the access aperture, it is an inherent characteristic of insertion of implant within the human body to create an access aperture before the implant is inserted and then closing the same aperture after the implantation is completed.

Regarding the removal of a shaft and replacement of a second shaft, the device is capable of being replaced by a second shaft without removing both the body and the head is required. The specification clearly disclose that the shaft can be loosened during operation in order to adjust the shaft length or the rotation position of the shaft, therefore, if necessary the shaft is capable of being replaced if the shaft is damage, or get loosened in the intramedullary canal or the patient needs a longer shaft.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steps above for the purpose of replacing an old shaft by a new one.

Regarding claims 42-51; 52-59 & 60-74, Muhlhausler et al does not disclose a plurality of shafts. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a modular implant having a plurality of different shafts in order to select the appropriate shaft for each patient. Additionally, it would have been obvious to one

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having ordinary skill in the art at the time the invention was made to have a plurality of different shafts capable of being replaced if the shaft is damaged, or get loosened in the intramedullary canal or the patient needs a longer shaft.

Regarding claims 44, 45, 55 & 63-64, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the threaded connection of the shaft with the body with a Morse taper connection because at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the threaded connection with the Morse taper connection because Applicant has not disclosed that by having a Morse taper connection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the threaded connection because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify Muhlhauser et al reference to obtain the invention as specified in claims 44 & 45.

Regarding the shaft removal, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Dwyer et al reference by using a delivering tool, such as a pliers, in order to insert or remove the prosthetic shaft.

Allowable Subject Matter

Claims 19-23 and 76-78 are allowed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

November 30, 2009.